

**LEGISLATIVE SERVICES AGENCY
OFFICE OF FISCAL AND MANAGEMENT ANALYSIS**

301 State House
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FISCAL IMPACT STATEMENT

LS 7307

BILL NUMBER: SB 275

DATE PREPARED: Jan 1, 2001

BILL AMENDED:

SUBJECT: Clinical Trials.

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**FUNDS AFFECTED: X GENERAL
DEDICATED
FEDERAL**

IMPACT: State & Local

Summary of Legislation: This bill defines "associated treatment cost" for purposes of payment for medically necessary treatment and drugs and devices associated with clinical trial treatments. The bill requires group health benefit plans for public employees, individual and group accident and sickness insurance policies, and individual and group health maintenance organization (HMO) contracts to provide coverage for associated treatment cost. The bill prohibits dollar limits, deductibles, copayments, or coinsurance requirements on coverage of associated treatment cost that are less favorable than those for physical illness generally. It also requires health benefit plan administrators, insurers, and HMOs to submit annual reports to the Commissioner of the Department of Insurance describing clinical trials for which associated treatment cost was covered. The bill also requires the Insurance Commissioner to compile information gathered and make an annual report available to the public. The bill establishes the Work Group on Health Care Coverage for Associated Treatment Cost to study and make recommendations regarding costs and benefits of the coverage required under the bill.

Effective Date: July 1, 2001.

Explanation of State Expenditures: The bill potentially could increase the premium cost incurred by the state in providing health insurance benefits to state employees. In addition, the bill would have a cost impact on the Department of Insurance.

Impact on State Employee Health Care Costs: This bill mandates insurance coverage for the costs of medically necessary treatment associated with clinical trials. The coverage mandate potentially could have an impact on future costs faced by health plans providing health benefits to state employees. These additional costs would presumably be passed through to the state and state employees via higher premiums and enrollment fees. At the beginning of 1999, one of the current state employee health plans estimated that the coverage mandate would not lead to an increase in its cost. Another of the current state employee health plans, however, estimated that the coverage mandate would lead to an increase in its costs in the amount of

1% of premiums. By agreement with the state employees, the state agrees to pay 93.5% of any increase in the total premiums for both single and family coverage during the life of the agreement. Employees will pick up the remaining 6.5% of any increase.

Impact on Department of Insurance: The bill also establishes the Work Group on Health Care Coverage for Associated Treatment Cost for the purposes of assessing the costs and benefits of health care coverage for medically necessary treatment associated with clinical trials. The 9-member Work Group is to: (1) develop a methodology for assessing the economic and clinical impact of this type of health care coverage; (2) collect from health care providers and payers aggregate clinical and financial data on insured treatments to assess differences in associated treatment costs and clinical outcomes; and (3) make recommendations to the Insurance Commissioner pertaining to coverage for associated treatment costs. The Work Group is to be appointed before January 1, 2002, and will be in existence until the Work Group submits its final report to the Legislative Council on or before June 30, 2003.

Maryland passed similar legislation in 1998 and is in the early planning stages of their effort. The fiscal analysis for the Maryland bill estimated that the requirements of the bill could be met by a medical economist and an administrative assistant at a cost of about \$85,000 per year. This type of study could also be contracted out to universities or consulting firms, with the final costs being more or less depending upon the specific requirements of the contract.

A \$35 per diem plus travel expenses is to be paid to the seven Work Group members who would not be state employees. This would amount to at least \$245 per meeting for per diem cost if all attended. The Work Group will be staffed and administered through the Department of Insurance.

Explanation of State Revenues:

Explanation of Local Expenditures: Similar to the state, increased premiums and enrollment fees arising from the mandated coverage of medically necessary treatment associated with clinical trials may result in additional costs to local governments and school corporations purchasing health benefits from insurance companies and HMOs for their employee health benefit plans. However, provision of such coverage may not necessarily imply additional budgetary outlays since employer responses to increased health benefit costs may include: (1) greater employee cost sharing in health benefits; (2) reduction or elimination of health benefits; (3) reduction in the size of the workforce eligible for health benefits; and (4) passing costs onto workers in the form of lower wage increases than would otherwise occur.

Explanation of Local Revenues:

State Agencies Affected: All; Department of Insurance.

Local Agencies Affected: Local Governments and School Corporations.

Information Sources: Keith Beesley, Indiana Department of Personnel, 232-3062.
Liz Carroll, Indiana Department of Insurance, 232-2406.
Kathleen Loughran, Maryland Department of Insurance, (410) 468-2014.